II. REMARKS

Preliminary Remarks:

Claims 42, 48, and 49 are amended, and claims 60-70 are canceled.

Claim 42 is amended to be directed to a chimeric anti-human CD23 antibody wherein the light chain variable domain consists of the polypeptide encoded by nucleotides 58-390 of SEQ ID NO: 1, the heavy chain variable domain consists of the polypeptide encoded by nucleotides 58-423 of SEQ ID NO: 2, and the constant region is a human constant region selected from the group consisting of human gamma –1 and human gamma –3 constant regions. Support for the amendment is found in the specification on pages 44-45, which describe the light chain variable domain of antibody 6G5 as the polypeptide encoded by nucleotides 58-390 of SEQ ID NO: 1, and on pages 47-49, which describe the heavy chain variable domain of antibody 6G5 as the polypeptide encoded by nucleotides 58-423 of SEQ ID NO: 2.

Claim 48 is amended to be directed to a chimeric anti-human CD23 antibody wherein the light chain variable domain consists of the polypeptide encoded by nucleotides 67-387 of SEQ ID NO: 3, the heavy chain variable domain consists of the polypeptide encoded by nucleotides 58-411 of SEQ ID NO: 4, and the constant region is a human constant region selected from the group consisting of a human gamma –1 constant region and a human gamma –3 constant region. Support for this amendment is found in the specification on pages 51-52, which describe the light chain variable domain of antibody 5E8 as the polypeptide encoded by nucleotides 67-387 of SEQ ID NO: 3, and on pages 53-54, which describe the heavy chain variable domain of antibody 5E8 as the polypeptide encoded by nucleotides 58-411 of SEQ ID NO: 4.

Claim 49 is also amended to be directed to a chimeric anti-human CD23 antibody wherein the light chain variable domain consists of the polypeptide encoded by nucleotides 67-387 of SEQ ID NO: 3, the heavy chain variable domain consists of the polypeptide encoded by nucleotides 58-411 of SEQ ID NO: 4, with the exception that the asparagine codon encoded by nucleotides 289-291 of SEQ ID NO: 4 is replaced with a lysine codon. As discussed above for claim 48, support for this amendment is found in the specification on pages 51-52 and 53-54, which respectively describe the light and heavy chain variable domains of antibody 5E8. Replacement of the asparagine codon with a lysine codon is described, for example, on page 55, lines 20-30.

Claims 60-70 are canceled as being redundant.

Patentability Remarks:

Claims 42, 48, and 49 and their dependent claims were rejected under 35 U.S.C. §112, first paragraph, for non-enablement and lack of written description of a chimeric anti-human CD23 antibody wherein the light and heavy chain variable domains comprise the polypeptides encoded by SEQ ID NOs: 1 and 2, respectively, or the polypeptides encoded by SEQ ID NOs: 3 and 4, respectively. The claims are amended to be directed to a chimeric anti-human CD23 antibody wherein the light and heavy chain variable domains consist of the polypeptides encoded by the disclosed nucleotide sequences. The specific nucleotide sequences in SEQ ID NOs:1-4 encoding the light and heavy chain variable domains are described in the specification on pages 44-45, 47-49, 51-52, and 53-54, respectively, and are specified in the amended claims without inclusion of the disclosed leader sequences. At the time the priority application was filed, it was well-known by persons in the art that the leader sequences are cleaved off during secretion of the antibody.

Claim 49 and its dependent claims were also rejected under 35 U.S.C. §112, first paragraph, for lack of written description (new matter) because the sequence listing shows glutamine, not asparagine, at codon 75 (see page 12 of the office action). The reference to codon 75 in claim 49 reflects the antibody codon numbering scheme shown on page 54 of the specification. To ensure that the mutated site identified in the claim is consistent with the sequence listing, claim 49 is amended to specify that the asparagine codon that is replaced with a lysine codon is encoded by nucleotides 289-291 of SEQ ID NO: 4, which is shown as codon 75 in the sequence on page 54 of the specification. The position of the mutated site in SEQ ID NO:4 can be verified by comparing the sequence of 5' primer M1653 in Table 5 on page 59, which was used to introduce the mutation, to the nucleotide sequence of SEQ ID NO:4.

The office action states that claims 61-69, directed to a pharmaceutical composition, are rejected under 35 U.S.C. §112, first paragraph, because the specification does not adequately teach how to use the claimed pharmaceutical composition for the treatment of *any* disease, so that undue experimentation would be required to use the claimed pharmaceutical composition. This ground of rejection is without merit. As discussed in the previous response, the application provides experimental data that demonstrates that the claimed composition acts as a drug *in vivo* to inhibit IgE production in experimental hu-SCID mice that have human immune systems. As taught in the specification, many pathological conditions (e.g., asthma, allergic rhinitis, atopy) are mediated by IgE (see pages 75-78), and suppression of IgE synthesis in a patient with such a condition is generally regarded as a

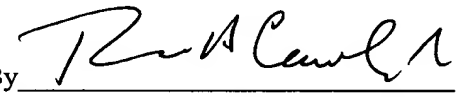
therapeutic strategy for treating the condition. Persons skilled in the art would therefore regard the disclosed experimental *in vivo* data as providing a reasonable expectation that administration of the claimed pharmaceutical composition to a person suffering from an IgE-mediated pathological condition such as those described in the specification would provide therapeutic benefit to the treated individual. The office action does not offer any scientific evidence or rationale that would cause one skilled in the art to doubt the therapeutic efficacy of the claimed pharmaceutical composition. The Applicants submit that the requirements of 35 U.S.C §112, 1st paragraph, are met by the present application with regard to claims drawn to a pharmaceutical composition.

The applicants respectfully submit that the original specification provides written description for the amended claims and enables persons skilled in the art to use the claimed invention successfully without undue experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Conclusion

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If any points remain in issue, which the examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,
PILLSBURY WINTHROP, LLP

By 

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